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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO.   |
|--|-------------|----------------------|---------------------|--------------------|
| 10/685,187   | 10/14/2003  | Robert A. Casper     | P-5352C1            | 4211               |
| 26253  | 7590        | 02/09/2005           | EXAMINER            |                    |
| DAVID W. HIGHET, VP AND CHIEF IP COUNSEL<br>BECTON, DICKINSON AND COMPANY<br>1 BECTON DRIVE, MC 110<br>FRANKLIN LAKES, NJ 07417-1880 |             |                      |                     | MENDOZA, MICHAEL G |
| ART UNIT   |             | PAPER NUMBER         |                     |                    |
| 3731   |             |                      |                     |                    |

DATE MAILED: 02/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/685,187             | CASPER ET AL.       |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Michael G. Mendoza     | 3731                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 14 October 2003.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-25 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12 January 2004</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### ***Double Patenting***

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1, 3, 4, 6-11, 15, 20, 22-25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-32 of U.S. Patent No. 6644309. Although the conflicting claims are not identical, they are not patentably distinct from each other because the application claims are merely broader than the patent claims. The structural limitations set forth in claims 1, 3, 4, 6-11, 15, 20, 22-25 of the instant application are also claimed in the patent, e.g., a tubular pressure member, a pressure member outlet, a valve having an outlet and an inlet, a dosing member having a chamber, a chamber inlet, a medicament and membranes.

3. Claims 2, 5, 8, 12, 13, 14, 16-18, 19, and 21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-32 of U.S. Patent No. 6644309 in view of US 6443152 to Lockhart et al. The application claims are broader in some respects and adds features in other respects.

The structural limitations set forth in claims of the instant application are also claimed in the patent, e.g., a tubular pressure member, a pressure member outlet, a valve having an outlet and an inlet, a dosing member having a chamber, a chamber inlet, a medicament and membranes. The difference between claims 2, 12, 13, 14, 18, 19, and 21 of the instant application and the claims of the patent is the penetration member.

4. Lockhart et al. teaches a penetration member for delivering fluid pressure to a cartridge. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include the penetration member of Lockhart et al. to allow opening of the cartridge with less effort.

5. As to claim 5 of the instant application, the application claims are broader in some respects and adds features in other respects. The structural limitations set forth in claims of the instant application are also claimed in the patent, e.g., a tubular pressure member, a pressure member outlet, a valve having an outlet and an inlet, a dosing member having a chamber, a chamber inlet, a medicament, and membranes. The difference between claim 5 of the instant application and the claims of the patent is the collapsible bulb.

6. Lockhart et al. teaches a collapsible bulb for delivering fluid pressure to a cartridge. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include the collapsible bulb of Lockhart et al as alternative means for applying fluid pressure.

7. As to claim 8, 16, and 17 of the instant application, the application claims are broader in some respects and adds features in other respects. The structural limitations

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set forth in claims of the instant application are also claimed in the patent, e.g., a tubular pressure member, a pressure member outlet, a valve having an outlet and an inlet, a dosing member having a chamber, a chamber inlet, a medicament, and membranes. The difference between claims 8, 16, and 17 of the instant application and the claims of the patent is that the patent claims are silent in regards to the physical state of the medicament (powder or liquid).

8. Lockhart et al. teaches the use of a powder or liquid medicament. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a powder or liquid medicament depending on what type of ailment is being treated. Furthermore, the cartridge of the patent claims is fully capable of housing either a medicament in powder or liquid form.

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**Contacts**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Mendoza whose telephone number is (571) 272-4698. The examiner can normally be reached on Mon.-Fri. 8:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Glenn Dawson can be reached on (571) 272-4694. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MM

  
GLENN K. DAWSON  
PRIMARY EXAMINER